IN THE CLAIMS:

Please amend claims 1, 2, 3, 4, 7, 13, 18, 25, 32 and 35 as indicated below.

This listing of claims below will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Amended) An oral controlled release pharmaceutical formulation comprising

a plurality of inert beads coated with a therapeutically active agent, said inert beads incorporated into said formulation in an amount sufficient to provide a desired therapeutic effect,

a barrier layer over said ~~core~~ beads containing said therapeutically active agent, said barrier layer comprising hydroxypropylmethylcelllose,

a controlled release layer over said barrier layer comprising an aqueous dispersion of plasticized ethylcellulose in an amount sufficient to obtain a controlled release of said active agent when said formulation is exposed to an environment fluid, said coated ~~substrate~~ beads being cured at a temperature greater than the glass transition temperature of the aqueous dispersion of plasticized ethylcellulose for at least about 24 hours.

2. (Amended) The formulation of claim 1, wherein said ~~substrate is~~ beads are coated with said controlled release layer to a weight gain from about 2 to about 30%.

3. (Amended) The formulation of claim 1, wherein said therapeutically active agent is selected from the group consisting of anti-histamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, ~~phsychotropics~~ psychotropics, antidiarrheals, mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

4. (Amended) The formulation of claim 1, wherein said active agent is an opioid analgesic chosen from the group consisting of hydromorphone, oxycodone, dihydrocodone, codeins,

dihydromorphine, morphine, buprenorphine, salts of any of the foregoing, and mixtures of any of the foregoing.

5. (Original) The formulation of claim 1, wherein a plurality of said coated, cured beads are placed in a capsule in an amount sufficient to provide an effective controlled release dose when contacted by an aqueous solution.

6. (Original) The formulation of claim 1, further comprising a second barrier layer over said controlled release layer, said second barrier layer comprising hydroxypropylmethylcellulose.

7. (Amended) The formulation of claim 1, wherein said controlled release coating further comprises a release-modifying agent in an amount effective to modify the rate of release of said active agent from said cured, coated ~~substrate~~ beads.

8. (Original) The formulation of claim 7, wherein said release-modifying agent is selected from the group consisting of a hydrophilic polymer, a semi-permeable polymer, an erosion-promoting polymer, an agent capable of making microporous lamina, a poreformer and mixtures of any of the foregoing.

9. (Original) The formulation of claim 8, wherein said coating comprises from about 0.1% to about 70% of said release-modifying agent.

10. (Original) The formulation of claim 8, wherein said release-modifying agent is selected from the group consisting of hydroxypropylmethylcellulose, lactose, metal stearates and mixtures of any of the foregoing.

11. (Original) The formulation of claim 1, wherein a portion of the amount of said active agent included in said formulation is incorporated into an outer coating.

12. (Original) A method for obtaining an oral controlled release formulation of a therapeutically active agent, comprising:

coating pharmaceutically acceptable inert beads with a therapeutically active agent;

thereafter coating said beads with a barrier layer comprising hydroxypropylmethylcellulose;

thereafter applying a controlled release layer onto said beads, said controlled release layer comprising a sufficient amount of a plasticized ethylcellulose to obtain a predetermined controlled release of said therapeutically active agent when said coated beads are exposed to an environmental fluid, said plasticized ethylcellulose being applied to said beads as an aqueous dispersion;

curing said controlled release layered beads at a temperature greater than the glass transition temperature of the aqueous dispersion of plasticized ethylcellulose for at least 24 hours, and

thereafter optionally applying a second barrier coating to said beads.

13. (Amended) The method of claim 12, further comprising preparing said ~~substrate~~ coated beads for oral administration by placing a sufficient quantity of cured coated beads into a gelatin capsule.

14. (Original) The method of claim 12, further comprising coating said controlled release beads with an outer layer comprising said therapeutically active agent.

15. (Original) The method of claim 12, wherein said barrier agent comprises hydroxypropylmethylcellulose.

16. (Original) The method of claim 12, further comprising applying said controlled release coating onto said beads to a weight gain from about 2 to about 25%.

17. (Original) The method of claim 12, wherein said therapeutically active agent is selected from the group consisting of antihistamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, psychotropics, antidiarrheals,

mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

18. (Amended) The method of claim 12, wherein said active agent is an opioid analgesic chosen from the group consisting of hydromorphone, oxycodone, dihydrocodone, codeins, dihydromorphine, morphine, buprenorphine, salts of any of the foregoing, and mixtures of any of the foregoing.

19. (Original) The method of claim 12, further comprising including a release-modifying agent in said controlled release coating an amount effective to modify the rate release of said active agent from said cured, coated beads.

20. (Original) The method of claim 19, wherein said release-modifying agent is selected from the group consisting of a hydrophilic polymer, a semi-permeable polymer, an erosion-promoting polymer, an agent capable of making microporous lamina, a pore-former, and mixtures of any of the foregoing.

21. (Original) The method of claim 20, wherein said coating comprises from about 0.1% to about 70% of said release-modifying agent.

22. (Original) The method of claim 20, wherein said coating comprises from about 0.1% to about 50% of said release-modifying agent.

23. (Original) The method of claim 20, wherein said coating comprises from about 0.1% to about 25% of said release-modifying agent.

24. (Original) The method of claim 20, wherein said release-modifying agent is selected from the group consisting of hydroxypropylmethylcellulose, lactose, metal stearates, and mixtures of any of the foregoing.

25. (Amended) A solid controlled release formulation, comprising a plurality of pharmaceutically acceptable inert beads coated with a therapeutically active agent, said

formulation comprising an amount of said beads sufficient to provide a desired effect when said. formulation is orally administered to a patient, said beads coated with said therapeutically active agent being overcoated with a barrier layer comprising hydroxypropylmethylcellulose, said barrier coated beads being coated with a controlled release layer of plasticized ethylcellulose in an amount sufficient to obtain a controlled release of said therapeutically active agent when said formulation is exposed to a gastrointestinal fluid, said ethylcellulose being applied to said beads as an aqueous dispersion, said coated beads being cured at a temperature greater than the glass transition temperature of the aqueous dispersion of plasticized ethylcellulose for at least about 24 hours, to cause individual ethylcellulose particles in said coating to coalesce and to gradually slow the release of said therapeutically active agent when said formulation is exposed to aqueous fluid, until an endpoint is reached at which said cured coated substrate, when subjected to in-vitro dissolution, releases said active agent in amounts which do not vary at any time point along the dissolution curve by more than about 20% of the total amount of active agent released, when compared to the in-vitro dissolution of said coated beads prior to curing.

26. (Original) The formulation of claim 25, wherein said cured, coated beads provide the same rate of release immediately after curing to said endpoint, and after subsequent exposure to. accelerated storage conditions of one month at a temperature of 37° C and at a relative humidity of 80%.

27. (Original) The formulation of claim 25, wherein said cured, coated beads provide the same rate of release immediately after curing to said endpoint, arid after subsequent exposure to accelerated storage conditions of one month at a temperature of 40° C and at a relative humidity of 75%.

28. (Original) The formulation of claim 25, wherein said controlled release coating is applied on said barrier coated beads to a weight gain from about 2% to about 25%.

29. (Original) The formulation of claim 25, wherein a plurality of said coated, cured beads are placed in a capsule in an amount sufficient to provide an effective controlled release dose when contacted by an aqueous solution.

30. (Original) The formulation of claim 25, wherein said cured, coated formulation when administered orally provides effective blood levels of said systemically active therapeutic agent for about 24 hours.

31. (Original) The formulation of claim 25, which includes a controlled release coating sufficient to obtain a controlled release of said active agent when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37° C from about 12.5% to about 42.5% (by wt) active ingredient released after 1 hour, from about 25% to about 55% (by wt) active agent released after 2 hours, from about 45% to about 75% (by wt) active agent released after 4 hours and from about 55% to about 85% (by wt) active agent released after 8 hours.

32. (Amended) The formulation of claim 25, wherein said controlled release coating further comprises a release-modifying agent in an amount effective to modify the rate of release of said therapeutically active agent from said cured, coated ~~substrate~~ beads.

33. (Original) The formulation of claim 32, wherein said release-modifying agent is selected from the group consisting of a hydrophilic polymer, a semi-permeable polymer, an erosion-promoting polymer, an agent capable of making microporous lamina, a poreformer and mixtures of any of the foregoing.

34. (Original) The formulation of claim 25, which provides therapeutically effective blood levels of said systemically active therapeutic agent when administered orally for about 12 hours.

35. (Amended) The formulation of claim 25, wherein said therapeutically active agent is an opioid analgesic chosen from the group consisting of hydromorphone, oxycodone, dihydrocodone, codeins, dihydromorphine, morphine, buprenorphine, salts of any of the foregoing, and mixtures of any of the foregoing.

36. (Original) The formulation of claim 25, further comprising a second barrier layer

overcoated on said controlled release coating.

37. (Original) The formulation of claim 36, wherein said second barrier layer comprises hydroxypropylmethylcellulose.

38. (Original) The formulation of claim 36, further comprising an outer coating comprising a loading dose of said therapeutically active agent.